

**REMARKS**

Reconsideration of the present application, as amended, is respectfully requested. The application, as amended, includes claims 39-60, pending and under consideration.

In the Office Action mailed November 26, 2004, claims 39-73 were pending. Claims 61-73 have been withdrawn from consideration, and claims 39-60 stand rejected. Reconsideration of the present application as amended in view of the remarks that follow is respectfully requested.

**Remarks Regarding Objection to Claim 50**

Claim 50 is objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. In support of this rejection, the Examiner states that, "The cod liver oil recited in Claim 50 does not fall in any of these categories of fluid base material [recited in claim 39 (mineral oils, silicone oils, plant-based oils, water and mixtures thereof)] since it is a fish-derived oil."

In reply, Applicant did not intend that original Claim 39 would be given a "closed" interpretation, requiring that the fluid base material can include nothing in addition to mineral oils, silicone oils, plant-based oils, water and mixtures thereof. In order to improve the clarity of this claim, Applicant has above requested entry of an amendment to Claim 39 to further clarify that the term "fluid base material" is to be given an open interpretation by inserting the term "comprising" into the claim. Specifically, Claim 39 is amended to specify that the composition includes "a fluid base material

comprising a member selected from the group consisting of mineral oil, silicone oil, plant-based oil, water and mixtures thereof.” In addition, claim 50 is amended to recite “wherein the fluid base material further comprises cod liver oil.” Upon entry of these amendments, Applicant submits that the objection to Claim 50 is overcome, and that claims 39 and 50 should be given an open interpretation.

**Remarks Regarding Rejection Under the Judicially-Created Doctrine of Obviousness-Type Double Patenting**

Claims 39-60 stand rejected under the judicially created doctrine of double patenting in view of U.S. Patent No. 6,627,178. The ‘178 patent issued from the parent of the present application and is commonly owned therewith. Applicant submits herewith a terminal disclaimer to moot this point, and withdrawal of the nonstatutory double patenting rejection is respectfully requested.

**Remarks Regarding Rejections of Claims Under 35 U.S.C. §103(a)**

**Remarks Regarding the Asserted Adams/Clark Combination**

In the outstanding Office Action, claims 39, 40, 44-48 and 54-58 are rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245). In traversal of this rejection, Applicant submits that the claimed invention is not obvious over this combination of references because there is no teaching, suggestion or motivation to be found in the cited references or in the prior art as a whole to modify the cited references in a manner that would be necessary to arrive at the present invention.

To accurately understand the suggestive effect of the cited references, and to fully appreciate what the cited references would suggest to one skilled in the art at the time of the invention, it is important to consider the art as a whole at the time the invention was made, including trends and beliefs in the field of diaper rash treatment and the perspective of a person skilled in the art. A person of ordinary skill in the art at the time of the present invention would have understood that each diaper rash treatment product available falls into one or both of the following two categories: “protective barrier” compositions and “active agent delivery” compositions. Of course, a given product could belong in both categories, i.e., a protective barrier composition could also include one or more active agents. While active agent delivery compositions could take a wide variety of physical forms (i.e., aqueous liquids, emulsions, creams, ointments, pastes, powders or other solids), the physical form of protective barrier compositions was and is relatively uniform: a highly viscous, typically hydrophobic, paste, ointment or cream. Such highly viscous compositions were believed to be necessary to provide a suitable protective barrier product.

Significant efforts have been made and significant resources have been devoted to efforts to identify the precise cause or causes of diaper rash, with the belief that this would enable the development of formulations that include active ingredients selected to address the cause more directly. Even in view of significant efforts to identify the specific cause of diaper rash, it was generally believed at the time the present application was filed, and is generally believed at this time, that the most important feature of a diaper rash treatment

composition is its ability to provide a physical, non-soluble barrier between urine and/or feces and the underlying skin. As stated at page 3 of the present application:

Because the suspected agents of diaper rash ... all possess diverse properties and require varied therapies, conventional methods of treatment for diaper dermatitis have been directed toward a straightforward attempt to minimize the contact of the skin with the feces or urine present in a soiled diaper. An artificial barrier is usually provided between the skin and the body waste to accomplish this... [Because] the exact components of urine or feces which act as factors or cofactors contributing to diaper dermatitis have never been precisely identified, the most effective method of treating diaper rash to date has been the artificial barrier.

In keeping with the trend of providing an artificial barrier in conventional treatments of diaper rash, a wide variety of highly viscous pastes, ointments and creams have been developed to be applied to skin in an effort to provide a suitable barrier to prevent skin contact with urine and/or fecal matter. Because urine is an aqueous liquid, and fecal matter sometimes also has a high water content, it has been long understood and widely accepted that, to be effective, the paste, ointment or cream should be formulated as a thick/viscous, hydrophobic preparation. It is, of course, understood that the application of such a product is messy and awkward due to the very features that make it a good barrier, i.e., its thick/viscous, oily, hydrophobic nature.

In view of this background, a person of ordinary skill in the art at the time of the present invention would have understood the limitations on the physical characteristics of ingredients in a barrier composition, and would not have been motivated to add ingredients into a barrier formulation that would reduce the viscosity or hydrophobicity thereof. Similarly, a person of ordinary skill in the art would have had no motivation to pluck ingredients from a "protective barrier" composition for inclusion in a liquid "active agent

delivery” composition. Applicant submits that many of the rejections asserted in the outstanding Office Action improperly suggest that it would have been obvious to pluck ingredients from such fundamentally different compositions and combine them into a diaper rash spray composition as described in the present application. It is worthy of note that both of the references cited in the outstanding Office Action as primary references (Adams et al. and Gebhart et al.) describe aerosol “active agent delivery” compositions. Specifically, the Adams et al. reference describes delivery systems selected from a wide variety of physical forms for delivering 8 Hydroxy Quinoline Sulfate or Parachlorometaxylenon to a skin irritation. The Gebhart et al. reference describes an aerosol composition for delivering vitamins A and D and d-pantothenyl to treat diaper rash. Neither of these compositions is capable of acting as a robust protective barrier.

In the first rejection asserted in the Action under §103, Adams et al. is cited by the Examiner as teaching a “diaper rash aerosol composition containing about 70% of water, jojoba oil and macadamia oil.” The Examiner further states,

The Adams et al. reference does not teach the component (2) of the instant claims. However, Clark et al. teach topical barrier composition containing 1-40% of micronized zinc oxide which has a mild astringent, protective and antiseptic action [and] a silicone material such as dimethicone or cyclomethicone, kaolin, calamine or talc, and petrolatum and/or mineral oils [and that] provide a superior long-lasting protective barrier formulation for managing diaper rash.

In reply, Applicant submits that neither Adams et al. nor Clark et al., nor any other reference of record in this case, provides any teaching, suggestion or motivation to modify the Adams et al or Clark et al. disclosures in a manner that would lead to the present

invention. It appears that the only link between the two references is that each describes a composition that can be used as a treatment for diaper rash; however, the assertion of obviousness ignores that a person of ordinary skill in the art at the time the of the invention would not have combined the references as suggested. The aerosol composition described in the Adams et al. reference is clearly not a barrier composition as is the Clark et al. composition. The Adams et al. reference describes a topical preparation utilizing a variety of different possible carrier systems to aid in caring for skin irritation, such as chapping, reddening, tenderness and the like, after the irritation begins to appear. Various formulations of carrier ingredients (i.e., in wipe-on stick form, lotion form, powder form, aerosol form, cream form, ointment form, jelly form or oil form) for delivering the active agent 8 Hydroxy Quinoline Sulfate or the active agent Parachlorometaxylenol are described. There is no mention of any sprayable composition that includes barrier-type ingredients, nor is there any suggestion therein of including same.

In making this rejection, the Examiner states that:

it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. such that to use zinc oxide and/or silicone oils and/or mineral oils. One having ordinary skill in the art would have been motivated to do this to obtain long-lasting skin protective formulation [sic] as suggested by Clark et al.

Indeed, the Clark et al. reference cited by the Examiner describes only highly viscous pastes, ointments and creams. However, the very viscous, oily nature of these compositions cuts against their selection for use in a system designed to atomize and spray a composition as described and claimed in the present application. A person of ordinary

skill in the art would find no motivation in these references to use a highly viscous paste, ointment or cream, or the ingredients thereof, in an aerosol formulation. A person of ordinary skill in the art would not have modified a highly viscous paste, ointment or cream protective barrier formulation to make it sprayable, and would not have selected ingredients thereof for inclusion in a spray-on diaper rash composition. It is notable that no prior art has been identified that is sprayable and that includes “a member selected from the group consisting of a solid particulate material, lanolin, petrolatum, cod liver oil, calendula, chamomile, and mixtures thereof.” Indeed, one of the very problems that the invention overcomes is the need for a sprayable composition that does include “a member selected from the group consisting of a solid particulate material, lanolin, petrolatum, cod liver oil, calendula, chamomile, and mixtures thereof.”

To establish a *prima facie* case of obviousness, the Examiner must identify in the prior art some teaching, suggestion or motivation to modify the cited references. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” (citations omitted). Manual of Patent Examining Procedure (“MPEP”) §2143.01. Some teaching in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984).

Furthermore, the prior art must be taken only for what it would teach or suggest to a person of ordinary skill in the art at the time of the invention, without using impermissible hindsight. As stated in MPEP § 2141.01:

“It is difficult but necessary that the decisionmaker forget what he or she has been taught ... about the claimed invention and cast the mind back to the time the invention was made..., to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 851 (1984).

Applicant submits that one having ordinary skill in the art at the time of the invention would not have derived any motivation from the cited references to make the modifications that the Examiner has asserted to be obvious and that would have been necessary to arrive at a method as recited in the present claims. Indeed, because the notion of a viscous paste, ointment or cream is directly at odds with the notion of a sprayable composition, Applicant submits that the referenced actually teach away from one another. When properly considered, the only suggestion of the presently claimed invention is provided by the present application.

Remarks Regarding the Asserted Gebhart/Moss Combination

In the outstanding Office Action, claims 39, 40, 44 and 54-58 are rejected under 35 U.S.C. §103(a), as being unpatentable over Gebhardt et al. (US 3,584,115) in view of Moss (US 4,816,254). In traversal of this rejection, Applicant submits that the claimed invention is not obvious over this combination of references because there is no teaching, suggestion



or motivation to be found in the cited references or in the prior art as a whole to modify the cited references in a manner that would be necessary to arrive at the present invention.

Gebhardt et al., like Adams et al. discussed above, describes “aerosol compositions for the treatment of skin irritations such as diaper rash.” The Examiner states that, “Gebhart et al. do not teach the component (2) of the instant claims,” but states that various missing ingredients are supplied by Moss. In reply, Applicant submits that there is no motivation to combine the Gebhart et al. and Moss references for the same reasons that there is no motivation to combine the Adams et al. and Clark et al. references. A person of ordinary skill in the art would find no motivation in these references to pluck an ingredient from a highly viscous paste, ointment or cream and include it in an aerosol formulation. Indeed, the very problem that the invention overcomes is the need for a sprayable composition that does include “a member selected from the group consisting of a solid particulate material, lanolin, petrolatum, cod liver oil, calendula, chamomile, and mixtures thereof.” Applicant therefore submits that the cited references do not teach or suggest a method as recited in the subject claims, and would not motivate a person of ordinary skill in the art to modify the references to arrive at the present invention.

Remarks Regarding the Asserted Adams/Clark/Boussouire Combination

In the outstanding Office Action, claims 41-43, 59 and 60 are rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) and further in view of Boussouira et al. (US 6,103,247). In traversal of this rejection, Applicant submits that the Adams et al. and Clark et al. references are not

properly combined for the same reasons as set forth above, and that the Boussouira et al. reference also fails to provide any motivation to combine the references. As such, Applicant submits that this rejection is also improper for at least the same reasons that the rejection of claims over a combination of Adams et al. and Clark et al. is improper.

Remarks Regarding the Asserted Adams/Gebhart/Mulder/Moss Combination

In the outstanding Office Action, claims 39, 49 and 50 are rejected under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Mulder (US 5,536,502) and Moss (US 4,816,254). In traversal of this rejection, Applicant submits that neither the Adams et al. reference nor the Gebhart et al. reference is properly combined with the Moss references for the same reasons as set forth above with respect to the Adams/Clark and Gebhart/Moss combinations, and that the Mulder reference also does not support this rejection. More specifically, the Mulder reference does not even relate to a diaper rash treatment composition. Rather, this reference describes ointments that can be used as medicaments for use in treating skin-tear injuries. Applicant submits that a person of ordinary skill in the art at the time of the present invention would not have looked to a reference describing a skin-tear medicament, and certainly would not have had any motivation to combine an ingredient described in this unrelated reference with ingredients described in the Adams et al., Gebhart et al. or Moss references. Applicant therefore respectfully submits that this combination of references likewise does not support the asserted rejection of claims 39, 49 and 50.

Remarks Regarding the Asserted Adams/Gebhart/Huffstutler Combination

In the outstanding Office Action, claims 39, 51 and 52 are rejected under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701). The Huffstutler reference is cited in the Action as teaching “using comfrey extract in topical compositions for its healing properties and ability to stimulate epithelial development in the case of skin damage or breakdown.” Without acquiescing in the propriety of this rejection, Applicant submits that this rejection is now moot in view of the above-presented amendment to claim 39, whereby the word “comfrey” is removed from the Markush Group recited in the claim. Applicant therefore submits that this rejection is inapplicable to claim 39, as amended, and thus, also inapplicable to claims 51 and 52, which depend therefrom. This amendment to claim 39 is submitted without prejudice to Applicant’s right to further pursue protection for the subject matter of the invention embodied in the pre-amended claim 39 at a later time in this or a continuing application.

Remarks Regarding the Asserted Adams/Gebhart/Huffstutler/Moss Combination

In the outstanding Office Action, claim 53 is rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701) and further in view of Moss (US 4,816,254). Applicant submits that claim 53, which depends indirectly from claim 39, is in condition for allowance for at least the same reasons that claim 39 is allowable (discussed above). Applicant therefore respectfully requests withdrawal of this rejection.

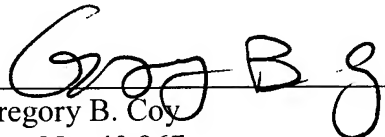
**Closing**

Applicant submits that, when properly considered, the only suggestion of the presently claimed invention is provided by the present application. One having ordinary skill in the art at the time of the invention would not have derived any motivation from the cited references to make modifications to the described compositions that would have been necessary to arrive at the invention as recited in the present claims, as amended. Applicant therefore respectfully submits that claims 39-60, as amended, are allowable over the cited references and request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 39-60, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: \_\_\_\_\_

  
Gregory B. Coy  
Reg. No. 40,967  
KRIEG DeVAULT LLP  
One Indiana Square  
Suite 2800  
Indianapolis, IN 46204-2079  
Tel.: (317) 636-4341  
Fax: (317) 636-1507